AUG 1 2000

510(K) SUMMARY

Elegra Millennium Enhanced Diagnostic Ultrasound system

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. **Submitted By:**
Siemens Medical Systems, Inc., Ultrasound Group
22010 S.E. 51st Street
Issaquah, WA 98027-7002

Contact Person:
Judi Hoffman
Regulatory Affairs

Phone: (425) 557-1229
FAX: (425) 391-9198

Date Prepared:
April 30, 2000

2. **Proprietary Name:**
Elegra Millennium Enhanced Ultrasound System

Common/ Usual Name:
Diagnostic Ultrasound System with Accessories

Classification Name:
21 CFR 892.1550

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX

3. **Predicate Device:**
K945072, 11/21/95, cleared as the Q4000, marketed as the Elegra Advanced with subsequent modifications.
K945773, 8/7/95, cleared as Versa, marketed as SONOLINE Versa Pro and SONOLINE Sienna with subsequent modifications.

4. **Device Description:**
The Elegra Millennium Enhanced is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bioeffect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in: B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging, or 3D imaging, on a CRT display.

The Elegra Millennium Enhanced, has been designed to meet the following product safety standards:

- UL 2601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment

- AIUM/NEMA, 1992, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, 1992 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN 60601-1
  - EN 60601-1-1
  - EN 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993 Biocompatibility

5. Intended Uses:

The Elegra Millennium Enhanced ultrasound imaging system is intended for the following applications: General Radiology, Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

6. Technological Comparison to Predicate Device:

Elegra Millennium Enhanced is substantially equivalent to the SONOLINE® Elegra, cleared via K945072, and modified via K950157, K961833, K981626, K980557 and K981528; and some features of the SONOLINE ® Versa, cleared via K945773, and modified via K962142, K962882, and K992046. All systems transmit ultrasonic energy into patients, then perform postprocessing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2000

Judi Hoffman
Senior Regulatory Affairs Specialist
Siemens Medical Systems, Inc
22010 S.E. 51st Street
Issaquah, WA 98029-7002

Re: K001400
Elegra Millenium Enhanced Diagnostic Ultrasound System
Regulatory Class: II
21 CFR 892.1550/Procode: 90 IYN
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX
Dated: April 30, 2000
Received: May 3, 2000

Dear Ms. Hoffman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Elegra Millenium Enhanced Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

CW2 Probe
P3-2 Phased Array Transducer
C5-2 Curved Array transducer
CX5-2 Curved Array Transducer
C7-3 Curved Array Transducer
VF7-3 Linear Array Transducer
EC9-4 Curved Array Transducer
VFX9-4 Linear Array Transducer
VF10-5 Linear Array Transducer
P9-4 Phased Array Transducer
VF13-5 Linear Array Transducer
VFX13-5 Multi-D Array Transducer
PX5-2 Phased Array Transducer
M7-4 Multiplane TEE Transducer

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for David A. Seymour

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **Elegra Millennium Enhanced Diagnostic Ultrasound System**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal		P	P	P	P	P	P		BMDC (P)	P	P
Abdominal		P	P	P	P	P	P		BMDC (P)	P	P
Intraoperative Abdominal					P						
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		BMDC (P)	P	P
Small Organ (Specify) **		P	P	P	P	P	P		BMDC (P)	P	P
Neonatal Cephalic		P	P	P	P	P	P		BMDC (P)	P	P
Adult Cephalic		P	P	P	P	P	P		BMDC (P)	P	P
Cardiac		P	P	P	P	P	P		BMDC (P)	P	P
Trans-esophageal		P	P	P	P	P	P		BMDC (P)	N	N
Transrectal		P	P	P	P	P	P		BMDC (P)	N	P
Transvaginal		P	P	P	P	P	P		BMDC (P)	N	P
Transurethral											
Intravascular											
Peripheral vessel		P	P	P	P	P	P		BMDC (P)	P	P
Laparoscopic											
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC (P)	P	P
Musculo-skeletal Superficial		P	P	P	P	P	P		BMDC (P)	N	N
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Prescription Use (Per 21 CFR 801.109)

David A. Bryan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001400

K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **CW 2 Probe for use with Elegra Millennium Enhanced**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal					P						
Abdominal					P						
Intraoperative Abdominal					P						
Intraoperative Neurological											
Pediatric					P						
Small Organ (Specify) **					P						
Neonatal Cephalic					P						
Adult Cephalic					P						
Cardiac					P						
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel					P						
Laparoscopic											
Musculo-skeletal Conventional					P						
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A Ayres

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **P3-2 Phased Array Transducer for use with Elegra Millennium Enhanced**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal		N	N	N	N	N	N		BMDC (N)	N	N
Abdominal		N	N	N	N	N	N		BMDC (N)	N	N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N	N	N	N		BMDC (N)	N	N
Small Organ (Specify) **											
Neonatal Cephalic		N	N	N	N	N	N		BMDC (N)	N	N
Adult Cephalic		N	N	N	N	N	N		BMDC (N)	N	N
Cardiac		N	N	N	N	N	N		BMDC (N)	N	N
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N	N	N	N		BMDC (N)	N	N
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **PX5-2 Phased Array Transducer for use with Elegra Millennium Enhanced**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal		N	N	N	N	N	N		BMDC (N)	N	N
Abdominal		N	N	N	N	N	N		BMDC (N)	N	N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N	N	N	N		BMDC (N)	N	N
Small Organ (Specify) **											
Neonatal Cephalic		N	N	N	N	N	N		BMDC (N)	N	N
Adult Cephalic		N	N	N	N	N	N		BMDC (N)	N	N
Cardiac		N	N	N	N	N	N		BMDC (N)	N	N
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N	N	N	N		BMDC (N)	N	N
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **C5-2 Curved Array Transducer for use with Elegra Millennium Enhanced**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal		N	N	N		N	N		BMDC (N)	N	N
Abdominal		N	N	N		N	N		BMDC (N)	N	N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N		N	N		BMDC (N)	N	N
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N		N	N		BMDC (N)	N	N
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N		BMDC (N)	N	N
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seguin
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001400

K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **CX5-2 Curved Array Transducer for use with Elegra Millennium Enhanced**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal		E	E	E		E	E		BMDC (E)	E	E
Abdominal		E	E	E		E	E		BMDC (E)	E	E
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		E	E	E		E	E		BMDC (E)	E	E
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		E	E	E		E	E		BMDC (E)	E	E
Laparoscopic											
Musculo-skeletal Conventional		E	E	E		E	E		BMDC (E)	E	E
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seguin
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001400

K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **P9-4 Phased Array Transducer for use with Elegra Millennium Enhanced**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal											
Abdominal		N	N	N	N	N	N		BMDC (N)	N	N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N	N	N	N		BMDC (N)	N	N
Small Organ (Specify) **											
Neonatal Cephalic		N	N	N	N	N	N		BMDC (N)	N	N
Adult Cephalic											
Cardiac		N	N	N	N	N	N		BMDC (N)	N	N
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N	N	N	N		BMDC (N)	N	N
Laparoscopic											
Musculo-skeletal Conventional		N	N	N	N	N	N		BMDC (N)	N	N
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Ferguson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **C7-3 Curved Array Transducer for use with Elegra Millennium Enhanced**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal		N	N	N		N	N		BMDC (N)	N	N
Abdominal		N	N	N		N	N		BMDC (N)	N	N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N		N	N		BMDC (N)	N	N
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N		N	N		BMDC (N)	N	N
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N		BMDC (N)	N	N
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **EC9-4 Curved Array Transducer for use with Elegra Millennium Enhanced**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (Specify) **		N	N	N		N	N		BMDC (N)	N	N
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal		N	N	N		N	N		BMDC (N)	N	N
Transvaginal		N	N	N		N	N		BMDC (N)	N	N
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Krogman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **M7-4 Multiplane TEE Transducer for use with Elegra Millennium Enhanced**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal		N	N	N	N	N	N		BMDC (N)	N	N
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **VF7-3 Linear Array Transducer for use with Elegra Millennium Enhanced**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal		N	N	N		N	N		BMDC (N)	N	N
Abdominal		N	N	N		N	N		BMDC (N)	N	N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N		N	N		BMDC (N)	N	N
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N		N	N		BMDC (N)	N	N
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N		BMDC (N)	N	N
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A Bergman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001400

Diagnostic Ultrasound Indications for Use Form

K001400

510 (k) Number (if known):

Device Name: **VF10-5 Linear Array Transducer for use with Elegra Millennium Enhanced**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal		N	N	N		N	N		BMDC (N)	N	N
Abdominal		N	N	N		N	N		BMDC (N)	N	N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N		N	N		BMDC (N)	N	N
Small Organ (Specify) **		N	N	N		N	N		BMDC (N)	N	N
Neonatal Cephalic		N	N	N		N	N		BMDC (N)	N	N
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N		N	N		BMDC (N)	N	N
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N		BMDC (N)	N	N
Musculo-skeletal Superficial		N	N	N		N	N		BMDC (N)	N	N
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001400

Diagnostic Ultrasound Indications for Use Form K001400

510 (k) Number (if known):

Device Name: **VFX9-4 Linear Array Transducer for use with Elegra Millennium Enhanced**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal		N	N	N		N	N		BMDC (N)	N	N
Abdominal		N	N	N		N	N		BMDC (N)	N	N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N		N	N		BMDC (N)	N	N
Small Organ (Specify) **		N	N	N		N	N		BMDC (N)	N	N
Neonatal Cephalic		N	N	N		N	N		BMDC (N)	N	N
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N		N	N		BMDC (N)	N	N
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N		BMDC (N)	N	N
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Hyman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **VF13-5 Linear Array Transducer for use with Elegra Millennium Enhanced**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		E	E	E	E	E	E		BMDC (E)	E	E
Small Organ (Specify) **		E	E	E	E	E	E		BMDC (E)	E	E
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		E	E	E	E	E	E		BMDC (E)	E	E
Laparoscopic											
Musculo-skeletal Conventional		E	E	E	E	E	E		BMDC (E)	E	E
Musculo-skeletal Superficial		E	E	E	E	E	E		BMDC (E)	E	E
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Legerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **VFX13-5 Multi-D Array Transducer for use with Elegra Millennium Enhanced**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		E	E	E	E	E	E		BMDC (E)	E	E
Small Organ (Specify) **		E	E	E	E	E	E		BMDC (E)	E	E
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		E	E	E	E	E	E		BMDC (E)	E	E
Laparoscopic											
Musculo-skeletal Conventional		E	E	E	E	E	E		BMDC (E)	E	E
Musculo-skeletal Superficial		E	E	E	E	E	E		BMDC (E)	E	E
Other (specify)											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

** small organs (breast, testes, thyroid, penis, prostate)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001400